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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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164

Applicants: Fayerer-Hosken et al.

Group Art Unit: 1614

Serial No.: 10/019,642

Examiner: Patrick S. Nolan

Filed: February 1, 2002

Docket No.: 235.00310101

(Int'l Filing Date: June 30, 2000)

Confirmation No.: 1056

Title: FERTILITY IMPAIRING VACCINE CONTAINING AVIAN ZONA PELLUCIDA PROTEIN  
AND METHOD OF USE

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P#6

Assistant Commissioner for Patents

P.O. Box 2327

Arlington, VA 22202

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

An itemized return postcard.

A Petition for Extension of Time for \_\_\_\_\_ month(s) and a check in the amount of \$\_\_\_\_\_ for the required fee.

An Information Disclosure Statement (2 pgs); copies of 4 applications; 1449 forms (12 pgs); and copies of 146 documents cited on the 1449 forms.

A check in the amount of \$\_\_\_\_\_, for \_\_\_\_\_.

A certified copy of a \_\_\_\_\_ application, Serial No. \_\_\_, filed \_\_\_\_\_, the right of priority of which is claimed under 35 U.S.C. §119.

Other: \_\_\_\_\_

Amendment \_\_\_\_\_ No Additional fee is required. \_\_\_\_\_ The fee has been calculated as shown:

Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Pending Before Filing (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x \$18 =	
Independent Claims				x \$84 =	
One or More New Multiple Dependent Claims Presented? If Yes Add \$280.00					
Total Additional Claim Fees Required					

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

**CERTIFICATE UNDER 37 C.F.R. §1.8:** The undersigned hereby certifies that this Transmittal Letter and the paper(s), as described hereinabove, are being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202, on this 16 day of February, 2003.

MUETING, RAASCH &amp; GEBHARDT, P.A.

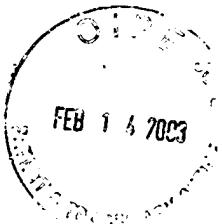
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26813

PATENT TRADEMARK OFFICE

By: Victoria A. Sandberg  
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PATENT  
Docket No. 235.003

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Applicants: Fayer-Hosken et al. ) Group Art Unit: 1614 TECH CENTER 1600/2900  
Serial No.: 10/019,642 ) Examiner: Patrick S. Nolan  
Confirmation No.: 1056 )  
Filed: February 1, 2002 )  
(Int'l Filing Date: June 30, 2000) )  
For: FERTILITY IMPAIRING VACCINE CONTAINING AVIAN ZONA  
PELLUCIDA PROTEIN AND METHOD OF USE

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
P.O. Box 2327  
Arlington, VA 22202

Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application. Consideration of each of the documents listed on the attached 1449 forms is respectfully requested. Pursuant to the provisions of M.P.E.P. § 609, Applicants further request that a copy of the 1449 forms, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Applicants also wish to bring the Examiner's attention to U.S. Provisional Application No. 60/070,375, filed January 2, 1998, U.S. Provisional Application No. 60/071,406, filed January 15, 1998, and U.S. Provisional Application No. 60/076,368, filed February 27, 1998. Copies of the three (3) aforementioned Provisional Applications are provided herewith. Also enclosed for the Examiner's information are copies of International Search Reports for International Application Nos. PCT/US98/27658, PCT/US00/18249, and PCT/US00/18051. Applicants also wish to bring the Examiner's attention to the following pending U.S. Applications, as well as any prior art and any provisional U.S. patent applications referenced therein. A copy of the below-listed pending U.S. Patent Application is provided herewith.

Information Disclosure Statement  
Applicants: Fayerer-Hosken et al.  
Serial No.: 10/019,642  
Confirmation No.: 1056  
Filed: February 1, 2002  
For: FERTILITY IMPAIRING VACCINE CONTAINING AVIAN ZONA PELLUCIDA PROTEIN AND METHOD OF USE

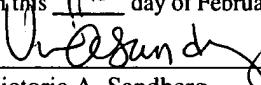
Page 2 of 2

**List of Pending Non-Published U.S. Patent Applications**

Applicant(s)	Application Number	Filing Date	Serial No. of Provisional Application to which listed Application claims priority
Fayerer-Hosken et al.	10/019,643	03/20/02	371 of PCT/US00/18249, which claims benefit of 60/142,308 and 60/177,903

It is believed that no fee is due, as this Information Disclosure Statement is filed prior to the receipt of any Action on the merits. However, in the event a fee is due, please charge any fee or credit any overpayment to Account No. 13-4895.

The Examiner is invited to contact Applicants' Representatives at the below-listed telephone number, if they can be of any assistance during prosecution of the present application.

CERTIFICATE UNDER 37 C.F.R. 1.8:
The undersigned hereby certifies that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202, on this <u>11<sup>th</sup></u> day of February, 2003.  Victoria A. Sandberg

Respectfully submitted for

**Fayerer-Hosken et al.**

By

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11 February 2003

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<b>INFORMATION DISCLOSURE STATEMENT</b> <i>FEB 1 1 2003</i>	Atty. Docket No.: 235.00310101	Serial No.: 10/019,642
	Applicant(s): Fayerer-Hosken et al.	Confirmation No.: 1056
	Filing Date: February 1, 2002 (Int'l Filing Date: June 30, 2000)	Group: 1614
	Information Disclosure Statement mailed:	February 11, 2003

**U.S. PATENT DOCUMENTS**

Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	3,992,520	11/16/76	Gwatkin			RECEIVED FEB 19 2003
	4,436,727	03/13/84	Ribi			
	4,436,728	03/13/84	Ribi et al.			
	4,520,019	05/28/85	Ribi et al.			TECH CENTER 1600/2900
	4,579,945	04/01/86	Schwartzman et al.			
	4,745,051	05/17/88	Smith et al.			
	4,795,634	01/03/89	Grimes et al.			
	4,803,070	02/07/89	Cantrell et al.			
	4,806,352	02/21/89	Cantrell			
	4,866,034	09/12/89	Ribi			
	4,877,611	10/31/89	Cantrell			
	4,912,094	03/27/90	Myers et al.			
	4,987,237	01/22/91	Myers et al.			
	4,996,297	02/26/91	Dunbar			
	5,219,729	06/15/93	Hodgen			
	5,312,620	05/17/94	Ribi			
	5,348,866	09/20/94	Isojima et al.			
	5,552,141	09/03/96	Ribi			
	5,565,198	10/15/96	Edwards et al.			
	5,626,846	05/06/97	Dean			
	5,637,300	06/10/97	Dunbar et al.			
	5,641,487	06/24/97	Dean			

<b>EXAMINER</b>	<b>Date Considered</b>
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\*Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date If Appropriate
	5,656,488	08/12/97	Curtiss, III et al.			RECEIVED
	5,672,488	09/30/97	Dean			
	5,736,141	04/07/98	Brown et al.			FEB 19 2003
	5,976,545	11/02/99	Harris et al.			TECH CENTER 1600/2900
	5,981,228	11/09/99	Harris et al.			
	5,989,550	11/23/99	Harris et al.			
	6,001,599	12/14/99	Harris et al.			
	6,027,727	02/22/00	Harris et al.			

**FOREIGN PATENT DOCUMENTS**

Examiner Initial	Document Number	Date	Country	Class	Subclass	Translation	
						Yes	No
	EP 0 324 455 A2	07/19/89	EPO				
	EP 0 599 822 A2	06/01/94	EPO				
	GB 1 504 259	03/15/78	GB				
	WO 89/03399 A1	04/20/89	PCT				
	WO 93/14786 A1	08/05/93	PCT				
	WO 93/25231 A1 ✓	12/23/93	PCT				
	WO 94/11019 A1	05/26/94	PCT				
	WO 99/34825 A1	07/15/99	PCT				
	WO 00/37100 A2, A3	06/29/00	PCT				
	WO 01/02000 A3	01/11/01	PCT				

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	WO 01/02006 A2, A3 ,	01/11/01	PCT				
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**OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)**

Examiner Initial	Document Description
	Aitken et al., "The potential of the zona pellucida as a target for immunocontraception," <i>Am. J. Reprod. Immunol.</i> , 1996; 35:175-180.
	Ahuja et al., "Investigation of Sperm Receptors in Hamster Zona Pellucida by Using Univalent (Fab) Antibodies to Hamster Ovary," <i>J. Reprod. Fert.</i> , 1981 Mar.; 61(2):257-264.
	Altman et al., "Immunomodifiers in Vaccines," <i>Advances in Veterinary Science and Comparative Medicine</i> , Bittle et al., eds., 1989; 33:301-343.
	Bagavant et al., "Antifertility effects of porcine zona pellucida-3 immunization using permissible adjuvants in female bonnet monkeys ( <i>Macaca radiata</i> ): reversibility, effect on follicular development and hormonal profiles," <i>J. Reprod. Fertil.</i> , 1994 Sept.; 102(1):17-25.
	Bagavant et al., "Immunogenicity and contraceptive potential of a human zona pellucida 3 peptide vaccine," <i>Biol. Reprod.</i> , 1997 Mar.; 56(3):764-770.
	Baldridge et al., "Effective adjuvants for the induction of antigen-specific delayed-type hypersensitivity," <i>Vaccine</i> , 1997; 15(4):395-401.
	Barber et al., "Evaluation of somatic and reproductive immunotoxic effects of the porcine zona pellucida vaccination," <i>J. Exp. Zool.</i> , 2000 May 1; 286(6):641-6.
	Barber et al., "Immunolocalization of zona pellucida antigens in the ovarian follicle of dogs, cats, horses and elephants," <i>Theriogenology</i> , 2001 May 1; 55(8):1705-1717.
	Barber et al., "Possible mechanisms of mammalian immunocontraception," <i>J. Reprod. Immunol.</i> , 2000; 46:103-124.
	Benoff, "Carbohydrates and fertilization: an overview," <i>Mol. Hum. Repro.</i> , 1997; 3(7):599-637.
	Böer et al., "Eine Übersicht über bisher in Zoologischen Gärten angewandte methoden der Kontrazeption," <i>Zool. Garten N.F.</i> , 1996; 66(2):93-105 (including English language summary). /

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Examiner Initial		Document Description
		Booth et al., <i>Veterinary Pharmacology and Therapeutics</i> , 6 <sup>th</sup> Edition, Iowa State University Press, Ames, IA, 1988, Cover page, Publication page, Table of Contents, 4 pgs.
		Brandon et al., "Canine Immunosterilization with a Porcine Zona Pellucida Vaccine," <i>Theriogenology</i> , 1998; Vol. 49, Issue 1, 262.
		Chamberlin et al., "Human homolog of the mouse sperm receptor," <i>Proc. Nat'l Acad. Sci. USA</i> , 1990 Aug.; 87:6014-6018.
		Crichton, <i>Inorganic Biochemistry of Iron Metabolism</i> , Ellis Horwood Limited, Sussex, England, 1991, Cover page, Publication page, Table of Contents, and Bibliography, 9pgs.
		DeNardo, "Chapter 42: Dystocias," <i>Reptile Medicine &amp; Surgery</i> , Mader ed., W.B. Saunders Co., Philadelphia, PA, 1996; 370-374.
		Dietl et al., "Immunogenic potency of the zona pellucida," <i>Experientia</i> , 1982; 38:502-503.
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		Djerassi et al., "Planned Parenthood for Pets?" <i>Bull. Atomic Sci.</i> , 1973 Jan.; 29(1):10-19.
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		East et al., "Monoclonal Antibodies to the Major Protein of the Murine Zona Pellucida: Effects on Fertilization and Early Development," <i>Developmental Biology</i> , 1984 July; 104(1):49-56.

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	Faulkner, "Dimensions of the Pet Population Problem," <i>Journal of the American Veterinary Medical Association</i> , 1975 Mar. 1; 166(5):477-478.
	Fayerer-Hosken, "Clinical trials of canine immunosterilization vaccine: porcine zona pellucida (pZP)," Proposal to the Humane Society of the United States (HSUS), undated. (13 pgs.).
	Fayerer-Hosken et al., "Contraceptive potential of the porcine zona pellucida vaccine in the African elephant ( <i>Loxodonta africana</i> )," <i>Theriogenology</i> , 1999 Oct. 1; 52(5):835-846.
	Fayerer-Hosken et al., "Follicular Cystic Ovaries and Cystic Endometrial Hyperplasia in a Bitch," <i>JAVMA</i> , 1992 July 1; 201(1):107-108.
	Fayerer-Hosken et al., "Immunocontraception of African elephants," <i>Nature</i> , 2000 Sept. 14; 407(6801):149.
	Fayerer-Hosken, "Management of African elephant populations by immunocontraception," <i>Wildlife Soc. Bull.</i> , 1997; 25(1):18-21.
	Fayerer-Hosken et al., "Potential of the porcine zona pellucida (PZP) Being an Immunocontraceptive Agent for Elephants," <i>Theriogenology</i> , 1997 Jan. 1; 47(1):397.
	Feldmann et al., "Free-Roaming Urban Pets," <i>Health Services Reports</i> , 1973 Dec.; 88(10):956-962.
	Garza et al., "Mechanism of ovarian autoimmunity: induction of T cell and antibody responses by T cell epitope mimicry and epitope spreading," <i>J. Reprod. Immunol.</i> , 1998; 37: 87-101.
	Gilbert et al., "A method for separating the granulosa cells, the basal lamina and the theca of the preovulatory ovarian follicle of the domestic fowl ( <i>Gallus domesticus</i> )," <i>J. Reprod. Fertil.</i> , 1977; 50:179-181.
	Gupta et al., "Mapping of epitopes on porcine zona pellucida-3 $\alpha$ by monoclonal antibodies inhibiting oocyte-sperm interaction," <i>Bio. Repro.</i> , 1996 Aug.; 55(2):410-415.

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Examiner Initial	Document Description
	Harris et al., "Cloning and characterization of zona pellucida genes and cDNAs from a variety of mammalian species: The ZPA, ZPB and ZPC gene families," <i>DNA Seq. - J. Seq. Map.</i> , 1994; 4(6):361-393.
	Hasegawa et al., "Antifertility effect of active immunization with ZP4 glycoprotein family of porcine zona pellucida in hamsters," <i>J. Reprod. Immuno.</i> , 1992 Aug.; 22(2):197-210.
	Hasegawa et al., "Blocking effect of antisera to recombinant zona pellucida proteins (r-ZPA) on <i>in vitro</i> fertilization," <i>AJRI</i> , 2000; 44:59-64.
	Hopp et al., "Prediction of Protein Antigenic Determinants from Amino Acid Sequences," <i>Proc. Natl. Acad. Sci. USA</i> , 1981 June; 78(6):3824-3828.
	Howarth, "Research Note: Avian sperm-egg interaction: perivitelline layer possesses receptor activity for spermatozoa," <i>Poult. Sci.</i> , 1990 June; 69(6):1012-1015.
	"Inject® Maleimide Activated Carrier Proteins," Product Information. Pierce Chemical Company, Rockford, IL, 1997 March; 1-6.
	"Immunochemicals," Product Information, 2 pgs., Sigma Chemical Company, undated; 1274-1275.
	Irwin et al., "Direct Injection of a Recombinant Retroviral Vector Induces Human Immunodeficiency Virus-Specific Immune Responses in Mice and Nonhuman Primates," <i>J. Virology</i> , 1994 Aug.; 68(8):5036-5044.
	Jilek et al., "Antibodies Against Mouse Ovaries and Their Effect on Fertilization <i>In Vitro</i> and <i>In Vivo</i> in the Mouse," <i>J. Reprod. Fert.</i> , 1975; 42:377-380.
	Joyner, "Chapter 29: Theriogenology; Female Reproductive Disorders," <i>Avian Medicine: Principles and Application</i> , Ritchie et al. eds., Wingers Publishing, Inc., Lake Worth, FL, 1994; 758-774.
	Kaul et al., "Expression of bonnet monkey ( <i>Macaca radiata</i> ) zona pellucida-3 (ZP3) in a prokaryotic system and its immunogenicity," <i>Mol. Reprod. Dev.</i> , 1997 June; 47(2):140-7.

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	Kirkpatrick et al., "Applications of pig zona pellucida immunocontraception to wildlife fertility control," <i>Journal of Reproduction and Fertility Supplement</i> , 1996, 50:183-189.
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	Kirkpatrick, <i>Management of Wild Horses by Fertility Control: The Assateague Experience</i> , National Park Service Scientific Monograph, 1995; 36 pgs., NPS/NRASIS/NRSM-92/26, U.S. Department of the Interior.
	Koyama et al., "Studies on the epitope of pig zona pellucida recognized by a fertilization-blocking monoclonal antibody," <i>J. Reprod. Fertil. Suppl.</i> , 1996; 50:135-42.
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	Mahi-Brown et al., "Infertility in Bitches Induced by Active Immunization With Porcine Zonae Pelluciade," <i>J. Exp. Zool.</i> , 1982; 222:89-95.

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1600/2900

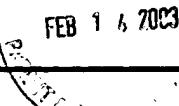
FEB 19 2003

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Examiner Initial	Document Description
	Mahi-Brown, "Ovarian Histopathology of Bitches Immunized with Porcine Zonae Pellucidae," <i>Am. J. Reprod. Immunol. Microbiol.</i> , 1988; 18:94-103.
	Miller et al., "Immunocontraception of white-tailed deer using native and recombinant zona pellucida vaccines," <i>Anim. Reprod. Sci.</i> , 2000; 63:187-95.
	Miura et al., "Two testicular cDNA clones suppressed by gonadotropin stimulation exhibit ZP2- and ZP3-like structures in Japanese eel" <i>Mol. Reprod. Dev.</i> , 1998 Nov; 51(3):235-42.
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<b>INFORMATION DISCLOSURE STATEMENT</b>  	Atty. Docket No.: 235.00310101	Serial No.: 10/019,642
	Applicant(s): Fayerer-Hosken et al.	Confirmation No.: 1056
	Filing Date: February 1, 2002 (Int'l Filing Date: June 30, 2000)	Group: 1614
	Information Disclosure Statement mailed:	February 11, 2003

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	Filing Date: February 1, 2002 (Int'l Filing Date: June 30, 2000)	Group: 1614
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